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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,919	06/29/2006	Jong Soo Woo	Q95721	1378

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EXAMINER	
CRAIGO, WILLIAM A	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
05/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/584,919	WOO ET AL.	
	Examiner	Art Unit	
	WILLIAM CRAIGO	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March, 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Acknowledgement is made of the response filed 15th March, 2010. In that response no claim amendments were filed. Claims 1-8 are treated on the merits in this action.

Maintained Rejections

The rejection of claims 1-6 under 35 U.S.C. 103(a) as being unpatentable over Woo, US 6107290, 22 August, 2000 in view of Deutsch, US 4897270, 30 January, 1990 and Alavi, JPharmPharmaceutSci, 5(3), 2002, pp. 234-244 is maintained.

The rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Woo, US 6107290, 22 August, 2000 in view of Deutsch, US 4897270, 30 January, 1990 and Alavi, JPharmPharmaceutSci, 5(3), 2002, pp. 234-244, as applied to claims1-6 above, and further in view of Murakami, US 3867414, 18 February, 1975 is maintained.

The rejection of claim 8 under 35 U.S.C. 103(a) as being unpatentable over Woo, US 6107290, 22 August, 2000 in view of Deutsch, US 4897270, 30 January, 1990, Alavi, JPharmPharmaceutSci, 5(3), 2002, pp. 234-244, and Murakami, US 3867414, 18 February, 1975 as applied to claim 7 above, and further in view of James, US 4865851, 12 September, 1989 is maintained.

Response to Arguments

Applicant's arguments filed 15th March, 2010 have been fully considered but they are not persuasive.

Applicant asserts the Combination of Woo, Deutch, and Woo fail to teach all and every elements of claims; that Deutch does not suggest the polymers as claimed.

This is not persuasive because Deutch suggests the use of methacrylic acid and its copolymers and specifically mentions Eudragit polymers in combination with cefuroxime axetil. While it is true the specific polymers Eudragit E and Eudragit E30D are not the same polymers as claimed, it is the suggestion of the genus of methacrylic acid and its esters thereof which points to the polymers recited in Alavi in combination with the sucrose fatty acid ester. The genus of methacrylic acid and its esters is small (methyl and ethyl ester) and one of ordinary skill would have expected similar results from either polymer. Alavi teaches the sucrose stearate improves the coating fomulation because there is no magnesium counterion which promotes flocculation in the formulation with anionic polymers.

Applicant asserts there is no motivation to combine Woo, Deutch, and Alavi to reach the claimed invention.

This is not persuasive because Deutch expressly suggests methacrylic acid and esters thereof and Alavi expressly teaches the combination of sucrose stearate improves the formulation of anionic polymers as discussed above. Applicant argues there is no motivation because Alavi teaches the formulation in combination with a protein; however one of ordinary skill would have expected a coating composition to work with other active agents.

Applicant asserts the combination exhibits remarkably beneficial effects of less bitter taste, higher stability and higher bioavailability.

This is not persuasive because Woo discloses the use of an amorphous form increases bioavailability of cefuroxime axetil; Deutsch suggests methacrylic acid and esters thereof solve problems associated with masking the bitter taste; and Alavi discloses the combination of sucrose stearate with anionic polymers such as methyacrylic acid and esters thereof provides a more stable coating formulation. Accordingly, one of ordinary skill in the art would have expected these benefits.

Text of Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 rejected under 35 U.S.C. 103(a) as being unpatentable over Woo, US 6107290, 22 August, 2000 in view of Deutsch, US 4897270, 30 January, 1990 and Alavi, JPharmPharmaceutSci, 5(3), 2002, pp. 234-244.

Woo is directed to a non-crystalline cefuroxime axetil formulation for oral administration. The patent teaches a solid dispersant form of cefuroxime axetil for formulation which provides a non-crystalline (amorphous) dispersable solid form of cefuroxime axetil from a crystalline form of cefuroxime axetil by combination with a surfactant and a water insoluble inorganic carrier (col. 2, lines 51-54), as in instant claims 1-7.

Col. 3, lines 51-58 of Woo lists water insoluble additives including microcrystalline cellulose, cross-linked polyvinylpyrrolidone, and cross-linked sodium carboxymethylcellulose.

Page 5, line 11 of the instant application defines these ingredients as disintegrating agents. Therefore Woo teaches disintegrating agents as defined by applicant, see instant claims 1 and 2.

Woo is silent to the composition comprising a sucrose fatty acid ester and a methacrylic acid-ethylacrylate copolymer; however Deutsch (col. 3, lines 34-35) teaches that polymer systems based on methacrylic acid and esters thereof (a coating material see instant claim 4 and 5), such as Eudragit are useful in the formulation of cefuroxime axetil with a disintegrant.

Woo is silent to the composition comprising a sucrose fatty acid ester and a methacrylic acid-ethylacrylate copolymer; however, Alavi, pg 235, subheading *Rationale for the Selection of Ingredients and Processes*, teaches the

combination of Sucrose Stearate (ScSt), as a droplet stabilizer in drug formulations (a pharmaceutically acceptable additive, see instant claim 4), with Eudragit (methacrylic acid-ethylacrylate copolymers) to provide enteric coated microparticles.

It would have been prima facie obvious to one of ordinary skill in the art to combine the dispersible solid form of Woo with the methacrylic acid esters (Eudragit) taught in Deutsch and Alavi and the sucrose stearate taught by Alavi to provide a granule composition as in the instant claims. One of ordinary skill would have combined these elements because Woo teaches the dispersible solid formulation with a disintegrating agent confers high stability and bioavailability (Woo, col. 2, lines 15-20) to the active ingredient, Deutsch teaches the film coat serves to mask the bitter taste of cefuroxime axetil upon oral administration (Deutsch, col. 2, line 16), and Alavi teaches "Sucrose stearate (ScSt) was used as droplet stabilizer since it localizes at the interface between dispersed phase and dispersion medium promoting dispersion and preventing flocculation. Sucrose stearate was chosen over the more common droplet stabilizer Magnesium stearate because our screening studies showed that the latter was incompatible with anionic polymers (attributed to reaction of magnesium ions with the -CHO carboxylic group of the polymer) and also formed a less smooth coating due to lower solubility," therefore providing a more uniform coating of methyacrylic acid polymers. One of ordinary skill in the art could have combined the elements of the prior art as claimed by known methods, and in combination

each element merely performs the same function as it does in the prior art; further, all of the documents are directed to improvements in drug formulation.

In regards to claims 3 and 6; example 4 of Deutsch gives a general concentration for the film forming polymer, and the general concentration of sucrose stearate is described on pg. 236 of Alavi under *Experimental Design*. Generally, differences in concentration or temperature or the like will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such a concentration or temperature is critical.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). **MPEP 2144.05**

Claim 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Woo, US 6107290, 22 August, 2000 in view of Deutsch, US 4897270, 30 January, 1990 and Alavi, JPharmPharmaceutSci, 5(3), 2002, pp. 234-244, as applied to claims1-6 above, and further in view of Murakami, US 3867414, 18 February, 1975.

Woo, Deutsch, and Alavi are all silent with respect to the mix-melting, cooling and pulverization; however, Murakami teaches mix-melting an active ingredient with a nonionic surface active agent, cooling the melt mixture and then pulverizing the solid obtained either through colloid mill (abstract) or a mortar (example 3). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to prepare a cefuroxime axetil granule

composition comprising the steps of mixing the sucrose fatty acid ester and methacrylic acid-ethylacrylate copolymer, melting the mixture and adding the disitegrating agent and active ingredient, cooling the dispersion and pulverizing the cooled dispersion to obtain the granule because this method is taught in the prior art as an effective way to prepare an amorphous form of a crystalline active agent.

Claim 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Woo, US 6107290, 22 August, 2000 in view of Deutsch, US 4897270, 30 January, 1990, Alavi, JPharmPharmaceutSci, 5(3), 2002, pp. 234-244, and Murakami, US 3867414, 18 February, 1975 as applied to claim 7 above, and further in view of James, US 4865851, 12 September, 1989.

Woo, Deutsch, Alavi, and Murakami are silent with respect to the temperature of the melt; however col. 4, line 59 of James teaches a molten lipid dispersion of defuroxime axetil in the range of 60 to 80 degrees Celsius, preferably 65 to 70 degrees Celsius depending on the particular lipid material to be used. While this provides a temperature for spray atomization, it gives guidance as to the temperature required to disperse the defuroxime axetil into a fluid. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to provide a melt temperature of 60 to 75 degrees Celsius as in the instant claims because the claimed ranges overlap and lie inside ranges disclosed in the prior art.

In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. In re

Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). **MPEP 2144.05**

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CRAIGO whose telephone number is (571)270-1347. The examiner can normally be reached on Monday - Friday, 7:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

/WILLIAM CRAIGO/
Examiner, Art Unit 1615